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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,059	03/16/2004	Mark Gelfand	3659-87	1197
23117	7590	03/29/2006		
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER

3761

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/801,059		GELFAND ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Leslie R. Deak		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 January 2006 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 19-25 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,471,872 to Kitaevich et al.

Kitaevich discloses, in the specification and figures, the device as claimed by applicant. In particular, Kitaevich discloses a renal function replacement apparatus which may perform hemofiltration, hemodialysis, or ultrafiltration (see column 2, lines 45-63). The system further comprises a blood withdrawal tube 14, blood reinfusion tube 30, filter 24, filtrate output section 64 and pump 66, a biosensor 140, and a controller 12 (see column 6, generally, column 7, lines 21-35, column 9, lines 16-25). The apparatus

monitors patient parameters that may include patient cardiac output, or oxygen saturation in the blood, and that signal is compared to upper and lower values (which are considered to correspond to applicant's threshold and baseline values) and used to control the fluid pumping rates (increasing or decreasing the pumping rate) in the system (see column 3, lines 50-55, column 4, lines 28-37, column 8, lines 32-45). Kitaevich further discloses that the controller may be used in an automatic mode wherein one or more patient parameters are monitored during the hemofiltration operation (which includes an initial phase of blood filtration treatment as claimed by applicant). The controller then operates based on this real-time patient data, considering one or more specific parameters that are stored, at least briefly, in the controller's processor in order to automatically adjust the operation of the blood filtration device (see column 4, lines 37-43).

With regard to the step of storing a baseline feedback signal during an initial phase of blood filtration treatment, Kitaevich specifically discloses that patient parameters may be programmed into the controller at the start of the blood treatment procedure (see column 9, lines 16-35). Such programming is within the scope of applicant's claimed "initial phase" of blood filtration treatment, since setting up the machine and controller are part of the blood treatment procedure, and such programming may be called an "initial phase" of blood treatment.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,417,872 to Kitaevich et al as applied above, in view of US 4,739,492 to Cochran.

Kitaevich discloses, in the specification and figures, the device as claimed by applicant, with the exception of using a summation step to determine a feedback signal threshold. However, Cochran discloses a method of providing feedback control to a dialysis system comprising the step of adding an delivery temperature error value (based on a predetermined value) to a temperature obtained via feedback signal. The final delivery temperature error is used as a threshold to toggle the heater on and off during treatment (see column 10, lines 15-57). Cochran discloses that the procedure allows for improved parameter monitoring by comparing actual operating parameters to estimated operating parameters in order to provide more accurate blood treatment (see column 3, lines 15-20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the summation step disclosed by Cochran in the control algorithm disclosed by Kitaevich in order to provide for more accurate feedback control of the blood treatment system, as taught by Cochran.

***Response to Arguments***

6. Applicant's amendment filed 6 January 2006 has been entered and considered.

7. Applicant's arguments filed 6 January 2006 have been fully considered but they are not persuasive.

8. Applicant argues that levels selected by a human operator are not baseline feedback signals obtained during an initial phase of blood filtration treatment. However, it is the position of the examiner that the "initial phase" of a blood filtration treatment may include the connection of the patient to the apparatus and the programming of patient and treatment parameters into the machine. Therefore, the predetermined values selected by the human operator anticipate applicant's claim drawn to obtaining or using a baseline value obtained during an "initial phase" of treatment.

9. Applicant's arguments with respect to claim 21 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Leslie R. Deak', is written over the printed name.

Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
27 March 2006